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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/400,179 03/06/95 SUGANO

H 1123971-303

EXAMINER

MARTINELL, J

ART UNIT

PAPER NUMBER

26

1804

DATE MAILED:

06/21/95

18M2/0621

WHITE & CASE  
PATENT DEPARTMENT  
1155 AVENUE OF THE AMERICAS  
NEW YORK NY 10036-2787

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 03/06/95 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.        | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.             | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152.       |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/>   |

**Part II SUMMARY OF ACTION**

1. ☒ Claims 10-15 and 30-59 are pending in the application.

Of the above, claims 53, 54, 56, and 59 are withdrawn from consideration.

2. ☒ Claims 1-9 and 16-29 have been cancelled.

3. ☒ Claims 11-14, 30-35, 38-41, and 44-47 are allowed.

4. ☒ Claims 10, 15, 36, 37, 42, 43, 48-52, and 55-57 are rejected.

5. ☐ Claims are objected to.

6. ☐ Claims are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on                     . Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on                     , has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed                     , has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no.                     ; filed on                     .

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

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Art Unit 1805

Newly submitted claims 53, 54, 58, and 59 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons.

Claims 53, 54, 58, and 59 are drawn to polypeptides and are classified in Class 530, subclass 351. The inventions are distinct, each from the other because of the following reasons. The proteins of claims 53, 54, 58, and 59 are materially different from and are therefore separate and distinct from the plasmids and host cells of claims 10-15, 30-37, 49-51, 55, and 56. The processes for producing plasmids and transformed host cells of claims 38-48 are not needed to produce the proteins of claims 53, 54, 58, and 59, which proteins can be purified from naturally occurring sources or may be synthesized chemically. Additionally, the processes of claims 38-48 can be used for purposes other than the production of the proteins of claims 53, 54, 58, and 59, for example, the production of large amounts of sequence specific nucleic acids. Finally, the methods of claims 52 and 57 are not needed to produce the proteins of claims 53, 54, 58, and 59 because said proteins may be purified from naturally occurring sources or may be synthesized chemically.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 53, 54, 58, and 59 withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

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The disclosure is objected to because of the following informalities. A typographical error occurs in the sequences of claims 31, 55, 56, and 57. In each of the claims in line 4 of each sequence, "CAT" should be changed to "GAT" (compare to Table 5, position 9 of the mature sequence). Appropriate correction is required.

Claims 49-52 and 55-57 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to processes and host cells in which expression is shown. See M.P.E.P. §§ 706.03(n) and 706.03(z). The instant application does not enable the expression of  $\beta_1$  interferon in any and all hosts or any and all host cells. Applicants' arguments (paper no. 22, page 11 and Exhibit B) are not convincing because the host cells used are not mentioned. This is not an invitation to submit further evidence subsequent to a final Office action.

Claims 49 and 50 are each rejected over the other as being substantial duplicate claims. No difference is seen between the claims.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure. It is not evident that each of the plasmids and microorganisms mentioned in claims 10, 15, 36, 37, 42, 43, and 48 is permanently available to the public. A "Suggestion for the Deposit of Biological Material" is attached to this Office action. This attachment was

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inadvertently not attached to the Office action mailed January 14, 1994. The error is regretted. This objection and the following rejection are repeated for reasons already of record (e.g., Office action mailed January 14, 1994, page 2). Applicants' arguments (paper no. 22, pages 8-9) are not convincing. First, a catalog from 1991 cannot be used as evidence of availability for plasmids in the instant application because the effective filing date of the instant application extends to 1980. Second, applicants' assurance to provide availability for the term of any patent that issues on the instant application is inadequate to overcome the objection and rejection because availability is to be assured for the enforceable life of the patent, not the term of the patent (e.g., see Office action mailed January 14, 1994).

Claims 10, 15, 36, 37, 42, 43, and 48 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 11-14, 30-35, 38-41, and 44-47 are allowable over the prior art of record.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY

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ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 at (703) 305-3014. The faxing of such papers must conform with the rules published in the Official Gazette, 1156 OG 61 (November 16, 1993).

Any inquiry concerning this communication should be directed to J. Martinell at telephone number (703) 308-0296.

  
JAMES MARTINELL, PH.D.  
SENIOR LEVEL EXAMINER  
GROUP 1800